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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

May 23, 2014

MEMORANDUM

SUBJECT: Amendment to Risk Assessment for PMN P-13-0930 dated April 15, 2014

FROM: Doritza Pagán-Rodríguez, PhD
New Chemicals Screening and Assessment Branch
Risk Assessment Division (7403M)

THRU: Louis Scarano Branch Chief
New Chemicals Screening and Assessment Branch
Risk Assessment Division (7403M)

TO: Jesse Miller, Program Manager
New Chemicals Notice Management Branch
Chemical Control Division (7405M)

Attached please find updated human health risk calculations and conclusions for P-13-0930 based on updated exposure estimates for the general population presented in the Standard Review Exposure Report (04/09/2014.) This amendment does not affect the human health risk calculations or conclusions for workers' exposure presented in the Standard Review Risk Assessment: P-13-0930 (04/15/2014.) The main conclusion of this amendment is listed below, with details presented in the attached documents.

CONCLUSION: The MOEs calculated with the newest environmental exposure estimates indicate that there are no risks for developmental toxicity from environmental exposures to the PMN by the general population.

AMMENDMENT to RISK ASSESSMENT: P-13-0930

I. BACKGROUND[1]

PMN Structure

[redacted]

II. HUMAN HEALTH DATA USED TO DERIVED CONCLUSIONS ON THIS AMMENDMENT[1]

The available toxicity data for Bisphenol A (BPA) indicates that its most sensitive toxicity endpoint is developmental toxicity. The most sensitive developmental effect and species is delayed puberty in rats among the developmental data summarized by NTP. From the cited studies, the lowest reported LOAEL is 50 mg/kg/day for decreased daily production of sperm and an increase in the age of vaginal opening. In that study, pregnant Sprague-Dawley (SD) and Alderley Park (AP) Wistar derived rats were exposed by gavage during GD 6-21 to 0, 20 µg/kg/day, 100 µg/kg/day or 50/mg/kg/day of BPA. The sexual development of the pups was monitored until termination at postnatal day 90 for males and 98 for females. The only statistically significant effects observed in the study were decrements in sperm production and time of vaginal opening in the AP rats at 50 mg/kg/day.

III. RISK ASSESSMENT FOR HUMAN HEALTH –Amended Exposure and Risk Estimations

Exposure Estimations

The estimated exposures to P-13-0930 by the general population to the PMN were obtained from the Exposure Report dated on 04/09/2013 and are presented in Table 1.

Table 1. General Population Exposures to P-13-0930 in the form of Acute Daily Rate (ADR) and Lifetime Average Daily Dose (LADD)

Exposure Scenario			Water		Landfill	Stack Air		Fugitive Air	
Drinking Water			Fish Ingestion						
ADR		LADD	ADR	LADD	LADD	ADR	LADD	ADR	LADD
mg/kg/day									
MFG [redacted]	4.92E-05	---	1.06E-04	---	---	---	---	---	---
MFG [redacted]	---	1.63E-06	---	1.86E-06	---	---	---	---	---
MFG [redacted]	6.44E-05	---	1.90E-04	---	---	---	---	---	---
MFG [redacted]	---	2.94E-06	---	3.35E-06	---	---	---	---	---
USE	1.88E-05	---	3.95E-05	---	---	---	---	---	---
USE	---	4.86E-07	---	5.54E-07	---	---	---	---	---

Risk Calculations for General Population Exposure Scenarios

Estimated risks in the form of MOE using the LOAEL of 50 mg/kg/day for developmental toxicity and an acceptable MOE of 1000 to account for intraspecies and interspecies variations and LOAEL to NOAEL extrapolation are presented in Table 2.

Table 2. Calculated MOEs for General Population Exposures based on LOAEL of 50 mg/kg/day for Developmental Toxicity and estimated ADRs

Exposure Scenario	ADR (mg/kg/day)	divided into	LOAEL (mg/kg-d)		MOE (Acceptable MOE ≥1000)
MFG [redacted]): Drinking Water	4.92E-05	into->	50	=	1E06
MFG [redacted] Drinking Water	6.44E-05	into->	50	=	8E05
USE: Drinking Water	1.88E-05	into->	50	=	3E06
MFG [redacted] Fish Ingestion	1.06E-04	into->	50	=	5E05
MFG [redacted] Fish Ingestion	1.90E-04	into->	50	=	3E05
USE: Fish Ingestion	3.95E-05	into->	50	=	1E06

[1] Comprehensive background and toxicity information on P-13-0930 can be found in the [redacted] available on PMN Gold.